

REMARKS

I. INTRODUCTION

Claims 28-36, claims 38-52, and paragraph [0016] of the specification have been amended to remove minor informalities as noted by the Examiner in the Office Action. Independent claim 37 has been amended to clarify the subject matter, but not for any reason relating to patentability of these claims. The amendments to claims 28-52 have not been made for any reason relating to patentability thereof, and comply with the requirements as set forth in 37 C.F.R. § 1.121, and again it is asserted that they have not been made for any reason relating to patentability thereof. It is respectfully submitted that no new matter has been added.

II. OBJECTIONS TO CLAIMS AND THE SPECIFICATION SHOULD BE WITHDRAWN

In the Office Action, the Examiner objected to claims 28-36 and 38-52 because of informalities associated with proper dependency. As the Examiner shall ascertain, claims 28-36 and 38-52 have been amended above to address the minor issues raised by the Examiner. Accordingly, Applicants respectfully submit that the objection to the claims is now moot, and should therefore be withdrawn.

Further, in the Office Action, the Examiner objected to the Specification because of minor informalities associated with a grammatical error in the phrase "delivering the energy 160 the entire heart" in line 18 of page 7 of the originally-filed Specification. As the Examiner shall ascertain, paragraph [0016] has been amended above to address the minor issues raised by the Examiner. Accordingly, Applicants

respectfully submit that the objection to the Specification is now moot, and should therefore be withdrawn.

III. **REJECTIONS UNDER 35 U.S.C. §§ 102(b) AND 102(e) SHOULD BE WITHDRAWN**

Claims 27-52 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Patent Application Publication No. 2002/0095197 filed by Lardo et al. (the "Lardo Application"). Additionally, claims 27-52 stand rejected under 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Patent No. 6,811,562 issued to Pless et al. (the "Pless Patent"). It is respectfully asserted that neither the Lardo Application nor the Pless Patent disclose the subject matter recited in independent claim 27 and amended independent claim 37 of the above-referenced application, and claims which depend therefrom, for at least the reasons provided in greater detail herein below.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102, each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedures, § 2131; see also *Lindman Maschinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

A. **Independent Claims 27 and 37**

Applicants' invention, as recited in independent claim 27, relates to an arrangement for detecting or treating cardiac abnormalities and cardiac inconsistencies, which comprises, *inter alia*:

a fluid delivery system adapted to systemically introduce a fluid to a target area of a heart of a subject, wherein a volume of the

**target area which receives the fluid is less than a volume of the heart.**

Applicants' invention, as recited in independent claim 37, relates to an arrangement for detecting or treating cardiac abnormalities and cardiac inconsistencies, which comprises, *inter alia*:

a fluid delivery system adapted to introduce a fluid to a target area of a heart of a subject, wherein **a volume of the target area which receives the fluid is less than a volume of the heart,** and wherein **a location of the volume of the target area which receives the fluid is provided at a distance from a location of an introduction of the fluid to a portion of the subject.**

The Lardo Application relates to methods and devices for treating and curing cardiac arrhythmias using photo-chemotherapy or photodynamic therapy. (See Lardo Application, ¶ [0026]). The method includes administering a photosensitizing agent to a patient's cardiac tissue, from which abnormal signals causing arrhythmias arise and/or by normal tissues that assist in sustaining arrhythmias. (See *id.*, ¶¶ [0027-0028]). The agent may be administered in a variety of ways, including systemically, via an angioplasty catheter balloon, or by perfusing the agent directly into the coronary arteries. (See *id.*, ¶¶ [0028-0032]). The photosensitizing agent may then be activated through a variety illumination methods. (See *id.*, ¶¶ [0027] and [0035]).

The Pless Patent relates to procedures and devices for treating cardiac tissue by forming lesions in the tissue using photodynamic therapy techniques. (See Pless Patent, column 1, lines 7-9). The Pless Patent describes a means of detecting cardiac arrhythmias by using an electrocardiogram (EKG) to detect the electrical activity within the heart. (See *id.*, column 2, lines 47-60). Further, the Pless Patent describes a method that includes introduction of a photodynamic drug through, for example, an intravenous injection or local administration. (See *id.*, column 9, lines 42-45).

Additionally, the Pless Patent describes use of a light source to focus energy on a specific region on the heart to excite the photodynamic drug once it has been administered. (See *id.*, column 1, lines 19-41 and 47-59).

In clear contrast to the Applicants' claimed invention, the Lardo Application and the Pless Patent do not disclose an arrangement in which, *inter alia*, a fluid delivery system is adapted to *systemically* introduce a fluid to a target area of a heart of a subject, wherein a volume of the target area which receives the fluid is less than a volume of the heart, as explicitly recited in independent claim 27. Additionally, the Lardo Application and the Pless Patent in no way disclose an arrangement in which, *inter alia*, a fluid delivery system is adapted to introduce a fluid to a target area of a heart of a subject, wherein a location of the volume of the target area which receives the fluid is provided at a distance from a location of an introduction of the fluid to a portion of the subject and is less than the volume of the volume of the heart, as recited in amended independent claim 37.

With respect to independent claim 27, the Lardo Application and the Pless Patent only describe arrangements in which photodynamic or photosensitizing agents or compounds are introduced in a very general way. However, neither the Pless Patent nor the Lardo Application describe an introduction of a fluid *systemically* in a particular volume of tissue, much less that such volume *is less in volume than a volume of the heart*. Although the Lardo Application describes a systemic way for introducing the photosensitizing agent, at no point in the disclosure of the Lardo Application is there any discussion of a way to *systemically* introduce the agent in a volume of the heart *that is less than the volume of the heart*. (See Lardo Application, ¶¶ [0028-0032]). The

introduction arrangement described in the Pless Patent, as in the Lardo Application, would not allow for introduction of a drug to a specific target area ***which is less than a volume of the heart*** that is ***systemic***.

In addition, with respect to amended independent claim 37, the Lardo Application describes a non-systemic way of introducing the photosensitizing agent (through a angioplasty catheter balloon or similar device). However, the volume of the target area (the volume of the heart) which receives the fluid is ***not*** provided at a distance from a location of an introduction of the fluid to a portion of the subject (i.e. it uses a direct angioplasty catheter balloon). In fact, the Lardo Application only describes a way of ***directly*** introducing the fluid to the target area at the location of the target area. (See *id.*, ¶¶ [0030-0032]). Additionally, the Pless Patent describes that the photosensitizing drug may be applied locally, but it does not disclose how this may be accomplished in a way that would allow for the volume of the target area, which receives the fluid, to be at a distance from a location of an introduction of the fluid to a portion of the subject ***and*** to be less than the volume of the volume of the heart. (See Pless Patent, column 9, lines 46-58). As recited in amended independent claim 37, the location of the volume of the target area which receives the fluid ***must*** be provided at a distance from a location of an introduction of the fluid to a portion of the subject ***and must*** be less than the volume of the volume of the heart.

Similarly, the Pless Patent describes a systemic way of introducing a photosensitizing drug. (See Pless Patent, column 9, lines 42-45). However, the Pless Patent does not describe any way of introducing the drug specifically to a volume of the target area of the heart ***which is less than a volume of the heart***. The systemic

introduction described in the Pless Patent, as in the Lardo Application, would not allow, much less provide for a concentration of a drug at a specific target area which is less than a volume of the heart.

Accordingly, it is respectfully asserted that the Lardo Application and the Pless Patent do not disclose the recitation of claims 27 and 37 or the claims which depend therefrom.

B. Dependent Claims 35, 40, and 51

Further, regarding claims 35 and 40 and claim 51, these claims depend from independent claims 27 and 37, respectively. Accordingly, the comments provided above with reference to independent claims 27 and 37 are repeated herein.

In particular, claims 35 and 51 further recite that:

the scar tissue has a predetermined metabolism, and wherein the liquid is adapted to be received only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism.

Neither the Lardo Application nor the Pless Patent disclose an arrangement in which *a scar tissue target area has a predetermined metabolism and a liquid that is adapted to be received only by those areas of the heart having a metabolism which is greater than or equal to the predetermined metabolism*. The Examiner does not point to any section of the Lardo Application or the Pless Patent as allegedly disclosing such recited subject matter. Accordingly, it is respectfully asserted that the Lardo Application and the Pless Patent do not disclose the recitation of claims 35 and 51.

Claim 40 further recites that:

**the fluid delivery system is further adapted to locally introduce the fluid to the target area via a coronary vessel.**

Neither the Lardo Application nor the Pless Patent disclose an arrangement in which ***the fluid delivery system is further adapted to locally introduce the fluid to the target area via a coronary vessel.*** The Examiner does not point to any section of the Lardo Application or the Pless Patent as allegedly disclosing such recited subject matter. Although both the Lardo Application and the Pless Patent describe a way of locally introducing the fluid, neither describe a way of ***locally introducing the fluid via a coronary vessel.*** (See Lardo Application, ¶¶ [0030-0032]; Pless Patent, column 9, lines 46-58). Accordingly, it is respectfully asserted that the Lardo Application and the Pless Patent do not disclose the recitation of claim 40.

C. Summary

Therefore, for at least the reasons set forth herein above, Applicants respectfully assert that the rejection of claims 27-52 under 35 U.S.C. §§ 102(b) and 102(e) should be withdrawn.

**IV. CONCLUSION**

In light of the foregoing, Applicants respectfully submit that pending claims 27-52 are in condition for allowance. Prompt consideration, reconsideration and allowance of the present application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided below.

Respectfully submitted,

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